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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/543,264	04/05/2000	Benjamin D. Pless	459992000700	6469

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EXAMINER
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BRADFORD, RODERICK D

ART UNIT	PAPER NUMBER
3762	

DATE MAILED: 01/16/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	Application No.	Applicant(s)
	09/543,264	PLESS, BENJAMIN D.
	Examiner	Art Unit
	Roderick Bradford	3762

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

1) Responsive to communication(s) filed on 18 October 2002.

2a) This action is **FINAL**.                            2b) This action is non-final.

3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

4) Claim(s) 1-81 is/are pending in the application.

4a) Of the above claim(s) 15-17, 23-40, 54-56 and 66-81 is/are withdrawn from consideration.

5) Claim(s) 22, 41-45, 59, 60 and 62-65 is/are allowed.

6) Claim(s) 1-14, 18-21, 46-53, 57, 58 and 61 is/are rejected.

7) Claim(s) \_\_\_\_\_ is/are objected to.

8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

9) The specification is objected to by the Examiner.

10) The drawing(s) filed on \_\_\_\_\_ is/are: a) accepted or b) objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11) The proposed drawing correction filed on \_\_\_\_\_ is: a) approved b) disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12) The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

13) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) All b) Some \* c) None of:

- Certified copies of the priority documents have been received.
- Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
- Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

14) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) The translation of the foreign language provisional application has been received.

15) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

1) Notice of References Cited (PTO-892)

2) Notice of Draftsperson's Patent Drawing Review (PTO-948)

3) Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_\_.

4) Interview Summary (PTO-413) Paper No(s) \_\_\_\_\_.

5) Notice of Informal Patent Application (PTO-152)

6) Other: \_\_\_\_\_.

## DETAILED ACTION

### *Response to Arguments*

1. Applicant's arguments filed on October 18, 2002 have been fully considered but they are not persuasive. The arguments are moot in view of new grounds of rejection necessitated by amendment.

The Fischell et al reference meets the claim limitation because the length of the interval has not been defined.

In regards to clarification of the claims, claims 1-81 are pending. Claims 15-17, 23-40, 54-56 and 62-80 are withdrawn from consideration. Therefore claims 1-14, 18-22, 41-53 and 57-61 stand rejected.

The objection to the drawings has been withdrawn.

Applicant's election with traverse of Group I in Paper No. 7 is acknowledged. The traversal is on the ground(s) that the Examiner has not provided reasons and/or examples or show a "serious burden" will be placed on the Examiner. This is not found persuasive because proof of "notoriety" of "separate" status has been made in Paper No. 7 by showing that the subcombinations are distinct from each other because the subcombinations are shown to be separately useable. In addition they have acquired a separate status because of their recognized divergent subject matter and therefore present a serious burden to the examiner.

The requirement is still deemed proper and is still held FINAL.

Applicant's election with traverse of election of species in Paper No. 7 is acknowledged. The traversal is on the ground(s) that the basis for the election of

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species requirement has not been established. This is not found persuasive because applicant has not submitted evidence or identified such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In addition, the different species represent the different ways the pulse parameters can be used.

The requirement is still deemed proper and is still held FINAL.

***Claim Rejections - 35 USC § 102***

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

- (e) the invention was described in-
  - (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effect under this subsection of a national application published under section 122(b) only if the international application designating the United States was published under Article 21(2)(a) of such treaty in the English language; or
  - (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that a patent shall not be deemed filed in the United States for the purposes of this subsection based on the filing of an international application filed under the treaty defined in section 351(a).

2. Claims 1-7, 12, 18-21, 46, 50-53, 57 and 58 are rejected under 35 U.S.C. 102(e) as being anticipated by Fischell et al. U.S. Patent No. 6,161,045.

Referring to claims 1 and 50, Fischell discloses a method for treating abnormal neurological condition comprising, applying to brain tissue at least one electrical burst comprising a multiplicity of pulses and said pulses having pulse parameters and varying at least one of the pulse parameters during at least one electrical burst (column 5, lines 29-39).

Referring to claim 2, wherein at least two pulse parameters vary during the burst (column 5, lines 29-39).

Referring to claim 3, further comprising the step of applying the said at least one electrical burst in response to a detectable electrical activity of the brain (Fig. 1).

Referring to claim 4, wherein said electrical activity is an epileptiform electrical activity (Fig. 1).

Referring to claim 5, wherein said electrical activity predicts impending epileptiform electrical activity (column 3, lines 66, 67 and column 4, lines 1, 2).

Referring to claim 6, wherein said pulse parameters are selected from the group consisting of selected electrodes, pulse width, pulse amplitude, pulse polarity, and pulse-to-pulse interval (column 7, lines 29-35).

Referring to claim 7, wherein at least one pulse parameter is pulse-to-pulse interval (column 7, lines 29-35).

Referring to claim 12, wherein said method further comprising the step of incrementally increasing said pulse-to-pulse interval for at least a portion on the burst (column 6, lines 58-60).

Referring to claims 18, 20, 57 and 58, wherein said method further includes the step of detecting said electrical activity in the brain prior to initiating the application of said at least one electrical burst (column 6, lines 4-17).

Referring to claims 19 and 21, wherein said at least one pulse parameter is related to said detectable electrical activity (column 6, lines 50-53).

Referring to claims 46 and 50, at least a first electrical electrode (column 7, line 19), and at least an electrical signal source, said first electrical signal source initiating a stimulation burst to said electrode, said burst having pulse parameters (column 7, lines 27-35), which the pulse parameters vary during said burst (column 5, lines 29-39).

Referring to claim 52, wherein said electrical signal source is configured to vary pulse parameters selected from the group consisting of electrode choice, pulse width, pulse amplitude, pulse polarity, and applied pulse-to-pulse interval (column 7, lines 29-35).

Referring to claim 53, wherein the first electrical signal source is configured to vary said pulse parameters randomly, pseudo-randomly, fractally, incrementally increasing and decreasing, or effectively to avoid initiation of epileptiform activity (column 6, lines 58-60).

Referring to claim 57, wherein said at least a first brain electrical activity sensor is configured to detect epileptiform activity prior to initiating the application (column 6, lines 4-8).

#### ***Claim Rejections - 35 USC § 103***

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

4. Claims 8, 10 and 11 are rejected under 35 U.S.C. 103(a) as being unpatentable over Fischell et al. U.S. Patent No. 6,161,045.

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Referring to claim 8, Fischell discloses the claimed invention except for wherein said at least one pulse-to-pulse interval is between about 3 and 300 microseconds. It would have been an obvious matter of design choice to one skilled in the art to modify the pulse-to-pulse interval of Fischell to be between 3-300 microseconds, since applicant has not disclosed that a pulse-to-pulse interval being between about 3 and 300 microseconds provides any criticality and/or unexpected results and it appears that the invention would perform equally well with any pulse-to-pulse interval, such as the pulse-to-pulse interval as taught by Fischell as a means of treating epileptic activity.

Referring to claims 10 and 11, Fischell discloses the claimed invention except for further comprising the steps of pseudorandomly varying and fractally varying said pulse-to-pulse interval. It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the device as taught by Fischell, with the steps of pseudorandomly varying and fractally varying said pulse-to-pulse interval since it was well known in the art that pseudorandomly varying and fractally varying said pulse-to-pulse intervals are use an alternate means to adjust the intervals to help stop epileptic activity.

5. Claim 9 is rejected under 35 U.S.C. 103(a) as being unpatentable over Fischell et al. U.S. Patent No. 6,161,045 in view of Weijand et al U.S. Patent No. 5,792,212.

Referring to claim 9, Fischell fails to disclose a method further comprising the step of randomly varying said pulse-to-pulse interval. However, Weijand discloses a step of randomly varying said pulse-to-pulse interval (column 3, lines 66, 67 and column

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4, line 1) as another means of varying the pulse-to-pulse interval for controlling epileptic activity.

It would have been obvious to one having ordinary skill in the art at the time invention was made to modify the teachings of Fischell to further include the step of randomly varying said pulse-to-pulse interval, as taught by Weijand, as another means of varying the pulse-to-pulse interval for controlling epileptic activity.

6. Claim 13 is rejected under 35 U.S.C. 103(a) as being unpatentable over Fischell et al. U.S. Patent No. 6,161,045 in view of Ward et al. U.S. Patent No. 5,713,923.

Referring to claim 13, Fischell fails to disclose a method further comprising the step of incrementally decreasing said pulse-to-pulse interval. However, Ward discloses a step of incrementally decreasing said pulse-to-pulse interval (TABLE IV) as a more affective means of controlling seizures.

It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the teaching of Fischell to further include the step of incrementally decreasing said pulse-to-pulse interval, as taught by Ward, as a more affective means of controlling seizures.

***Allowable Subject Matter***

13. Claims 22, 41-45, 59 and 62-65 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

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***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Roderick Bradford whose telephone number is (703) 305-3287. The examiner can normally be reached on Monday - Friday 7 a.m. - 4 p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Angela Sykes can be reached on (703) 308-5181. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 872-9302 for regular communications and (703) 872-9303 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0858.

*R. Bradford*

*1/10/03*

R.B.

January 10, 2003

*cc*  
GEORGE R. EVANISKO  
PRIMARY EXAMINER

*1/10/03*